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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,784	11/03/2003	Jacques M. Dulin	7175-004US	5515
. 759	90 11/16/2005		EXAM	INER
Jacques M. Dulin, Esq.			ROYDS, LESLIE A	
Innovation Law Group, Ltd. 237 N. Sequim Avenue			ART UNIT	PAPER NUMBER
Sequim, ŴA 98382			1614	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No. Applicant(s)					
	10/700,784	DULIN, JACQUES M.				
Office Action Summary	Examiner	Art Unit				
	Leslie A. Royds	1614				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
Responsive to communication(s) filed on <u>31 Oc</u> This action is <b>FINAL</b> . 2b)⊠ This     Since this application is in condition for allowan closed in accordance with the practice under E	action is non-final. ace except for formal matters, pro					
Disposition of Claims						
4) ⊠ Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) 5 and 16-20 is/are wit 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-4 and 6-15 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or						
Application Papers						
···						
9)⊠ The specification is objected to by the Examiner.  10)□ The drawing(s) filed on is/are: a)□ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1)  Notice of References Cited (PTO-892)  2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date 12/4/03 & 2/17/05.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other:					

#### **DETAILED ACTION**

# Claims 1-20 are presented for examination.

Applicant's petition to make the instant application special under 37 C.F.R. 1.102(c)(1) is acknowledged by the Examiner.

Acknowledgement is made of Applicant's claim for priority under 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/423,539, filed November 4, 2002. Applicant's Information Disclosure Statements (IDS) filed December 4, 2003 (two pages) and February 17, 2005 (one page) have each been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449 (three pages total), the Examiner has considered the cited references.

Applicant's Preliminary Amendment filed October 31, 2005 has been received and entered into the application. Accordingly, original claim 3 has been amended and duplicate claim 3 has been cancelled.

In accordance with the MPEP at §708.02, examination of the present application has been accelerated in light of the petition filed October 14, 2005. Restriction of the instant claims was performed according to the procedure outlined in MPEP §708.02(VIII) and following standard practice as set forth in MPEP §800.

#### Requirement for Restriction/Election

Restriction of the claims of the present application was performed under 35 U.S.C. 121 because it contained multiple independent and patentably distinct inventions. Election of species was also performed under 35 U.S.C. 121 because the present application contained generic

claims drawn to a plurality of patentably distinct species such that a search for the entirety of the active ingredients claimed would have posed an undue burden on the Examiner.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-15, drawn to a medication delivery system for oral hygiene and a portable consumer package containing such a delivery system, classified in class 514, subclass 568, for example.
- II. Claims 16-20, drawn to a method for oral hygiene care, classified in class 514, subclass 568, for example.

The inventions are distinct, each from the other, for the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the presently claimed method for oral hygiene care can be practiced by employing conventional means, such as a toothbrush in combination with toothpaste, floss and an antibacterial and/or antiplaque mouthwash, to maintain proper oral hygiene.

Claims 3, 5-6 and 18-19 are generic to a plurality of disclosed patentably distinct species comprising a variety of active ingredients to be contained within the treatment composition. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

For example, claim 3 recites "an enzyme" (classified in class 435, subclass 183+) and, among others, a plant extract (classified in class 424, subclass 58), which would not be included as part of a coextensive search of any one other compound used in the claimed delivery system.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Jacques Dulin on Wednesday, November 9, 2005, a provisional election was made <u>without</u> traverse to prosecute the invention of Group I, claims 1-15, drawn to a medication delivery system for oral hygiene and a portable consumer package containing such a delivery system, and the species of benzoic acid as the active ingredient contained within the treatment composition.

A proper reply to the present Office Action will include an affirmation of this election.

Claims 5 and 16-20 are <u>withdrawn</u> from further consideration by the Examiner pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention.

The claims that are drawn to the elected invention and elected species of active ingredient are 1-4 and 6-15 and such claims are herein acted on the merits.

### Objection to the Oath/Declaration

The oath or declaration is defective because Applicant has not clearly stated the claim for priority. Applicant has clearly claimed the benefit of U.S. Provisional Patent Application No.

60/423,539, filed November 4, 2002, but partially entered the serial number of a copending PCT Application under the section claiming priority under 35 U.S.C. 365(c). Appropriate correction to the oath/declaration is required and must be completed in compliance with 37 CFR 1.67(a) identifying this application by serial number and filing date. See MPEP §§ 602.01 and 602.02.

### Objection to the Specification

Applicant's claim for priority under 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/423,539, filed November 4, 2002, has been noted at page 1 of the present disclosure, but the following amendment to the section "Cross-Reference to Related Cases" is suggested to more clearly define the present priority claim. Applicant is reminded that the following is a suggestion and acceptance of such a suggestion does not necessarily equate to the claims being free of the cited prior art:

---This is the Regular US Application and/or its PCT counterpart of US Provisional Application S.N. 60/423,539, filed 4 November, 2002, by the inventor, entitled "Oral Hygene Hygiene System, Dosage Units and Method", the priority of which is claimed under 35 US Code 119, and related treaties(e).---

# Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 9 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicant regards as the invention.

The MPEP sets forth the following at §2173:

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (See MPEP §2173).

The term "about" in the expressions "from about 3/16" to 7/16" and length ranging from about 1" to about 2"" (claim 7), "of about 5/16" and length of about 1 1/2"" (claim 9) or "said pouch ranges in width from about 1.75" to about 2.25"..." (claim 14), for example, is a relative term that renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of such a term would invite subjective interpretations of whether or not a particular dimension is included in or excluded from the present claims and what degree of variability outside the recited ranges is within the scope of the claims.

Furthermore, the Examiner also has noted the word "from" in present claims 7 and 14. For example, the word "from" in the phrase "from about 3/16" to 7/16" and length ranging from about 1" to about 2"" in present claim 7 indicates that the diameter is between 3/16" and 7/16" and the length is between 1" and 2". However, the use of the word "about" denotes that the diameter or the length may be slightly greater or slightly less than 3/16" in diameter, for example, or 1" in length, for example. Thus, it is not clear which is meant to be the limiting term. It is the Examiner's position that the public would not be informed of the boundaries of

what constitutes infringement of the present claims.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. §112, second paragraph and are, thus, properly rejected.

# Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kazdan (U.S. Patent No. 3,452,382; 1969).

Kazdan teaches a disposable, readily portable tooth cleansing device (considered to meet Applicant's limitation of "for oral hygiene" as recited in present claim 1; col.1, lines 11-16) comprised of a fibrous body, such as cotton (col.1, lines 11-12), preferably as a cotton pad in the form of cylindrical cotton rolls about 3/8 inch in diameter and 1 ½ inches long (col.4, lines 42-49; see present claims 1 and 7), which is coated and impregnated with a dentifrice (col.1, lines 11-16; see present claim 1) via immersing the cotton pad in an aqueous dispersion (considered to meet Applicant's limitation of a "liquid...state" as recited in present claim 2 and "wherein said composition is a fluid" as recited in present claim 4) and then dried (considered to meet Applicant's limitation of a "dry...state" as recited in present claim 2; col.3, lines 13-20), which is inserted into the human mouth (considered to meet Applicant's limitation of "to be received comfortably in a buccal vestibule" as recited in present claim 1; col.1, lines 35-40 and col.12,

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lines 10-16) and may contain other materials, such as medicants (col.2, lines 50-52; see present claim 1) or bactericides (considered to meet Applicant's limitation of an "anti-microbial compound or composition" as recited in present claim 3, for example; col.2, line 69-col.3, line 3).

Although the present claims are drawn to cotton roll having a diameter of 3/16" to 7/16" and a length of 1" to 2" (see present claim 7, for example), Kazdan expressly teaches cylindrical cotton rolls 3/8 inches in diameter and 1 ½ inches in length. Such a teaching directly anticipates the presently claimed invention as recited in claim 7 insofar as it reads on a cotton roll of 3/8 inch in diameter and 1 ½ inches in length. See MPEP §2131.03 for a discussion of the anticipation of ranges.

Furthermore, it is noted that Kazdan teaches that the impregnating bath contain about 5-35% by weight based on the total weight of the aqueous bath of solids, such solids including the binder, other cleansing additives (considered by the Examiner to include the disclosed bactericidal component; see col.2, line 69-col.3, line 3) and the abrasive and polishing components. While the reference does not expressly state that such an amount is an amount effective for the amelioration of bad breath conditions, there is no reason to doubt, absent factual evidence to the contrary, that such an amount would not have demonstrated efficacy in ameliorating bad breath conditions.

Moreover, it is noted that the limitation "for amelioration of bad breath conditions" as recited in present claim 3 amounts to no more than a recitation of the intended use of the compound and fails to impart any physical or material property to the composition that is not already present in the composition of the prior art of Kazdan. In addition, because Kazdan

expressly teaches the use of concentrations "within certain limits in order to achieve the optimum in results" (see col.4, line 75-col.5, line 4), such a teaching is considered to meet Applicant's limitation of an effective amount of the composition, absent factual evidence to the contrary.

# Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kazdan (U.S. Patent No. 3,452,382; 1969) in view of Wiesel (U.S. Patent No. 6,287,120; 2001), Vermeer (U.S. Patent No. 5,624,906; 1997), Julius (U.S. Patent No. 4,071,955; 1978), Speaker et al. (U.S. Patent No. 4,917,892; 1990) and Copelan et al. (U.S. Patent No. 5,133,971; 1992).

Kazdan teaches a disposable, readily portable tooth cleansing device (considered to meet Applicant's limitation of "for oral hygiene" as recited in present claim 1; col.1, lines 11-16) comprised of a fibrous body, such as cotton (col.1, lines 11-12), preferably as a cotton pad in the form of cylindrical cotton rolls about 3/8 inch in diameter and 1 ½ inches long (col.4, lines 42-49; see present claims 1 and 7), which is coated and impregnated with a dentifrice (col.1, lines 11-16; see present claim 1) via immersing the cotton pad in an aqueous dispersion (considered to meet Applicant's limitation of a "liquid...state" as recited in present claim 2 and "wherein said composition is a fluid" as recited in present claim 4) and then dried (considered to meet

Applicant's limitation of a "dry...state" as recited in present claim 2; col.3, lines 13-20), which is inserted into the human mouth (considered to meet Applicant's limitation of "to be received comfortably in a buccal vestibule" as recited in present claim 1; col.1, lines 35-40 and col.12, lines 10-16) and may contain other materials, such as medicants (col.2, lines 50-52; see present claim 1) or bactericides (considered to meet Applicant's limitation of an "anti-microbial compound or composition" as recited in present claim 3, for example; col.2, line 69-col.3, line 3).

The differences between the Kazdan reference and the presently claimed subject matter lie in that the reference does not teach:

- (i) the medication present in a gel state (see present claim 2);
- (ii) the use of benzoic acid as the active ingredient (see present claim 6);
- (iii) the use of a cotton roll including a core of absorbent cotton fibers and a sheath selected from a mesh braiding and a highly permeable woven or non-woven sheet material (see present claim 8); and
- (iv) the particular type of portable consumer package (see present claims 10-15) and the dimensions of such a package and the cotton rolls contained within such a package (see present claim 14, in particular).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

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(i) Kazdan expressly teaches compositions wherein the cotton roll in impregnated with a liquid formulation (considered to meet Applicant's limitation of "wherein said medication is in a state selected from a liquid...state" as recited in present claim 2) or wherein the cotton roll is impregnated with a liquid formulation and then subsequently dried (considered to meet Applicant's limitation of "wherein said medication is in a state selected from a...dry state" as recited in present claim 2). Although Kazdan does not expressly teach that the cotton roll may be impregnated with a gel formulation, such would have been *prima facie* obvious to the skilled artisan in light of what was known in the art at the time of the invention.

In this regard, Wiesel (U.S. Patent No. 6,287,120; 2001) is cited. Wiesel teaches the use of a non-woven, porous material as a carrier (see col.3, lines 66-67), wherein the material is impregnated or coated with an agent in the form of a gel or a paste or a solution and is then applied to the teeth (see col.4, lines 5-17).

In light of such a teaching, it would have been plainly obvious to one of ordinary skill in the art to impregnate the cotton pad of Kazdan with a gel formulation of the disclosed active ingredients, since such a type of impregnation into a porous surface was a method well known in the art for the preparation of oral care compositions. Motivation to use such a gel formulation flows logically from the fact that the increased viscosity of the gel would increase the resident time in contact with the teeth and gum tissue, thereby extending the therapeutic effect of the composition. Such a conclusion is further supported by Wiesel at col.2, line 64-col.3, line 7, which states, "Topically applied antiseptics, such as mouthwashes, are easily washed from the site of infection by salivation and routine mastication. Thus, a need exists for an oral

composition which is effective in combating growth of infection causing bacteria which is capable of adhering to the site of infection and being retained in the oral cavity."

(ii) Kazdan broadly teaches that a bactericide component may be employed in the disclosed tooth cleansing composition. While Kazdan does not expressly teach the use of benzoic acid as the bactericidal component of the composition, such a compound was well known in the art at the time of the invention as an antibacterial agent known to have efficacy in treating a wide variety of microorganisms.

In this regard, Vermeer (U.S. Patent No. 5,624,906; 1997) is cited. Vermeer teaches oral hygiene compositions comprising an antibacterial agent, such as benzoic acid, which was known to have activity against a wide variety of microorganisms at levels below those known to be harmful (see Vermeer, col.35, line 66-col.36, line 30; see, in particular, col.36, line 20).

It would, therefore, have been *prima facie* obvious to one of ordinary skill in the art to employ benzoic acid as the antibacterial agent of the composition disclosed by Kazdan because the efficacy of such an agent as an antibacterial agent was recognized and demonstrated in the prior art against a wide variety of microorganisms at non-toxic levels. Furthermore, motivation to employ such an agent in an oral care composition, such as that disclosed by Kazdan, flows logically from the previous use of such an agent as an antibacterial component of oral hygiene compositions of the prior art (see Vermeer, as previously cited).

(iii) Although Kazdan broadly teaches the use of a cylindrical cotton roll, the reference is silent as to the particular use of a cotton roll includes a core of absorbent cotton fibers and a sheath selected from a mesh braiding and a highly permeable woven or non-woven sheet material. However, in light of the knowledge generally available to one of ordinary skill in the

art at the time of the invention, the use of such cotton rolls would have been well within the purview of the skilled artisan.

In this regard, Julius (U.S. Patent No. 4,071,955; 1978) is cited to show that highly absorbent sponge-like materials were known in the art to be laminated with at least one layer of woven or non-woven fabric-like material, such as cotton gauze or cotton batting (see abstract, for example), which Julius teaches has the advantage of absorbing more than a conventional sponge composition and also that it does not leave lint behind in the oral cavity (col.2, lines 7-10 and 32-34). Speaker et al. (U.S. Patent No. 4,917,892; 1990) is cited to teach that braided cord was commonly used in dental applications to provide highly sustained localized topical drug delivery and to serve as a drug reservoir (col.1, lines 55-61).

In light of such teachings, it would have been *prima facie* obvious to one of ordinary skill in the art to employ a core of absorbent cotton fibers covered in either a mesh braiding or covered in a woven or non-woven sheet material. Motivation to employ such a type of cotton formulation flows logically from the desire to enhance absorbency of the composition and/or to sustain localized topical drug delivery by serving as a reservoir providing the active agent(s).

(iv) While Kazdan does not expressly teach the type of packaging material that is presently claimed, the use of any packaging known in the art would have been plainly obvious to the skilled artisan. Considering that the composition of Kazdan is meant for oral use, it would have been apparent to the skilled artisan that such an oral dosage form would necessarily require packaging for distribution and, furthermore, packaging that maintained the activity of the active ingredient(s) of the composition.

In this regard, Copelan et al. (U.S. Patent No. 5,133,971; 1992) is cited. Copelan et al. teach a comparable composition to that of Kazdan, comprised of a woven cotton fiber mat (col.4, lines 63-66) impregnated with cleaning agents and formulated into a dry or nearly dry composition fabric (col.2, lines 48-53), which is carried, ready for use, in a simple, edge sealed packet of protective material such as coated or uncoated paper that is adhesively or mechanically bonded at its edges while forming a generally rectangular pouch, and wherein the packet may be of foil or moisture impervious sheet plastic material (col.4, lines 28-37).

The use of such a packaging form would have been plainly obvious to one of ordinary skill in the art, since such a package was known in the art to be effective for retaining oral care compositions prior to use. Such a person would have been motivated to elect this particular type of packaging since it was known in the art to preserve sterility, sanitary conditions (i.e., by protecting the oral composition from environmental sources of germs, etc.) and to retain efficacy of the active ingredients by protecting such compositions from contacting water, and thereby activating said composition, prior to use.

While it is noted that Copelan et al. does not expressly teach that the package is resealable or pocket-sized, the formulation of a package with such properties would have been well within the purview of the skilled artisan, particularly when packaging a plurality of individual compositions such that the unused remainder could be resealed for later use without affecting the sterility and efficacy of the remaining composition(s), and, further, such that the composition is easily and discretely transported on one's person. In addition, the use of a box to contain a plurality of individually wrapped compositions would have been *prima facie* obvious to the skilled artisan. Such a person would have been motivated to do so to retain multiple

individually wrapped compositions in a receptacle that can be easily shipped, transported or

moved in order to facilitate distribution.

Furthermore, it is noted that the type of packaging in which the composition is retained

does not impart any physical, material or structural properties to the composition that patentably

distinguish the composition of the present claims from the composition of the prior art of

Kazdan.

Lastly, the determination of the optimum diameter or length of the cotton roll to be

employed in the disclosed composition would have been a matter well within the purview of the

skilled artisan. Such a determination would have been made in accordance with a variety of

factors, including, but not limited to, the size of the subject's mouth, the medicament

impregnated into the cotton roll, the dose of the medicament to be administered and patient

compliance with inserting the roll into the subject's mouth. Moreover, it is noted that where the

only difference between the prior art and the claims is a recitation of the relative dimensions of

the claimed composition, and wherein such a difference in the dimensions does not result in an

appreciable difference in function of the composition, then the presently claimed dimensions to

not patentably distinguish the present composition from that of the cited prior art.

Conclusion

Rejection of claims 1-4 and 6-15 is deemed proper.

No claims of the present application are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866,217-9197-(tolk-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

November 13, 2005

CHRISTOPHER S. F. LOW SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600